Stakeholder Meetings Summary

FDA Task Force on Consumer Information for Better Nutrition
Stakeholder Meetings
Executive Summaries

Date: March 13, 2003
Time: 3:00 – 5:00 p.m.
Location: Conference Room 4B-047, Harvey W. Wiley Federal Building

Subject: FDA Initiative on Health Claims for Food Labels

Attendees:

Food and Drug Administration:
Lester Crawford; Joseph Levitt; William Hubbard; Michael Landa; Peter Salsbury; William Allaben; Steven Bradbard; Joanne Lupton; Alan Rulis; Christine Taylor; Elizabeth Yetley; Kathleen Ellwood; Patricia Kuntze; Cynthia Wise; Elizabeth Robboy; Mary Lacey Reuther; Theresa Mullin

Federal Trade Commission:
Mary Engle; Pauline Ippolito

National Institutes of Health:
Van Hubbard

Health Professional Organizations:

Richard Allison, American Society for Nutritional Sciences
Ronna Biggs, National Association of Chain Drug Stores
Joseph Cranston, American Medical Association
Colleen Doyle, American Cancer Society (Participated via phone)
Richard Hamburg, American Heart Association
Brett Kay, National Health Council
Harry Preuss, American College of Nutrition
Larry Rundel, American Heart Association
Sandra Schlicker, American Society for Clinical Nutrition
Mary Watts, American Dietetic Association

Purpose: To brief the attendees on the Task Force and begin the process of hearing views on all aspects of the Task Force effort. Specifically, the Task Force wanted to hear the attendees' individual views on how to help facilitate the flow of information to consumers about the role of sound dietary practices in achieving and

maintaining good health, while assuring that such information is truthful, non-misleading, and based on sufficient scientific evidence.

Agenda: Welcome and Introductions
Overview on Health Claims for Food Labels
Informal Discussion with Participating Organizations
Summary

Meeting Summary:

Dr. Crawford opened the meeting and provided information about the Task Force and its purpose. The Task Force is charged with developing a framework that will facilitate consumers' access to good information on food and dietary supplements that is scientifically based. The Task Force is also charged with developing a consumer studies research agenda aimed at providing research needed to determine how best to present scientifically-based information to consumers in a non-misleading way, and at identifying the kinds of information shown to be misleading to consumers. The Task Force will make recommendations to the Commissioner in June 2003. FDA plans to share the report and summaries of Task Force meetings with stakeholder organizations. The report will include recommendations on qualified claims for conventional foods and a consumer studies research agenda to determine what is misleading to consumers.

Dr. Christine Taylor provided a brief overview on Health Claims for Food Labels. The overview included background information about FDA policy before 1990, overview of the provisions in the Nutrition Labeling and Education Act that provided for voluntary nutrition claims, explanation of the Health Claim Standard, information about FDA implementation of the health claim provision, discussion of the three *Pearson* Court Decisions and FDA's actions to comply with the court decisions regarding qualified claims for dietary supplements, discussion of FDA's decision to expand qualified health claims to conventional foods. Dr. Taylor concluded the overview with information on the establishment of the Commissioner's Consumer Health Information for Better Nutrition Initiative and the Task Force charged to make recommendations on provisions for making non-misleading claims.

Dr. Crawford led an informal discussion with the participants framed around the following six questions. Highlights from points made by the stakeholders in the discussion are summarized below.

1. What body of scientific evidence do you think should be adequate for a qualified health claim?
2. What types of safety concerns should be factored into FDA's decision making?
3. What specific claims do you think are currently ready for consideration under the new guidance?

4. On what issues are disclaimers valuable, or not valuable, in preventing consumers from being misled, and do you have data to support your view?
5. What kinds of empirical data should FDA rely upon to show that consumers are, or are not, mislead by claims?
6. Should conventional foods and dietary supplements be treated the same or treated differently, and why?

Participants were encouraged to provide written comments to the Public Docket (03N-0069).

Question 1: What body of scientific evidence do you think should be adequate for a qualified health claim?

It was suggested that a group of qualified experts needs to review the available evidence and make a decision on health claims. FDA has experts qualified to review the evidence and make the decision.

There is concern that the courts have not recognized the contributions to public health that FDA has made. FDA has been, and needs to continue to be, objective, flexible and responsive. FDA's ability to evaluate scientific evidence is not in question. However, a close look at the other public health factors involved needs to be taken.

The Task Force needs to take a close look at the definitions and explain the difference between weight of scientific evidence and significant scientific agreement. There's concern that consumers will not be able to understand qualified health claims and thus be confused. It was suggested that the Task Force should review the Keystone Dialogue. This discussed similar issues and recommended being flexible, objective and responsive. Until a clear definition of what significant scientific agreement evidence means is established, FDA will continue to go back to court to defend its decisions not to allow a specific health claim.

Health organizations, such as American Cancer Society and American Dietetic Association, have developed guides used to grade the evidence supporting a specific endpoint to be used by their members in recommending diets for patients with specific conditions. For example, the American Dietetic Association uses a four level grading system with Grade 1 being the strongest and Grade 4 being supported only by opinions.

It is difficult to determine the risks and benefits. Benefits are just now being realized for the consumption of certain foods. The evidence is now just starting to come in. The negatives need to be looked at as well as the positives. The negatives are not published so it will be difficult to use them as indicators of risks.

It was suggested that at least two good studies are needed to support any risk or benefit recommendation.

It was also suggested that FDA should consider harmonizing dietary supplement labels with conventional food labels.

Consumers will find it difficult to understand the information contained in a qualified health claim and disclaimer.

Question 2: What types of safety concerns should be factored into FDA's decision making?

Consumers often perceive health claims with a "more is better" attitude or belief. Consumer behaviors and understanding must be factored into the review.

The upper levels of intake and all side effects need to be evaluated. For example, some foods/nutrients that have been promoted to better the health of the general population are not being promoted and sometime even discouraged for patients with certain diseases. People with compromised systems may be more at risk with the use of health claims than the general population.

The safety risks need to be disclosed if they are known. However, safety concerns will not always be known. For example, some thought that beta-carotene would be helpful but a later study found higher rates of lung cancer in those who took it.

Question 3: What specific claims do you think are currently ready for consideration under the new guidance?

Most health claims are based on an ingredient in the food versus the food as a whole.

The effects of the health claim itself needs to be considered. What difference will the health claim make if it is on food? Will the claim increase consumption?

A buffer is needed to deal with issues of too much consumption.

The design of the food label should be reviewed again.

The problem with health claims for supplements or functional foods is they are not like drugs where a dose response can be shown. For example, studies have been done on garlic. There are a lot of different varieties of garlic and you get different results depending on the variety.

Question 4: On what issues are disclaimers valuable, or not valuable, in preventing consumers from being misled, and do you have data to support your view?

Consumers need simplicity. The disclaimers need to be something than can be remembered easily.

Some feel the claims on dietary supplements are not understood by consumers and are therefore not valuable. A health claim statement that says something is good for you and then has a disclaimer that says it has not been evaluated confuses consumers. Some think the written disclaimer part of a qualified health claim on a food will be ignored and not read. FDA should consider developing a graphic that would communicate the strength of the evidence that supports the claim.

It was suggested FDA consider a 2 "grade" level approach, one to indicate the claim is supported by scientific evidence and the other to indicate that the claim is not supported by scientific evidence.

Education of consumers about the disclaimer, picture system or whatever FDA chooses is a must. FDA must educate, educate, and educate.

Question 5: What kinds of empirical data should FDA rely upon to show that consumers are, or are not, misled by claims?

More consumer research needs to be done with more "real" situations. Conduct nationwide surveys and follow-up with focus groups/mall intercepts rather than telephone surveys. Consumers need to be shown the sample warning labels or disclaimers. FDA needs to understand how consumers react to them and what message the consumer receives from the information.

Question 6: Should conventional foods and dietary supplements be treated the same or treated differently, and why?

Some feel the use of qualified health claims for conventional foods will confuse consumers and this is a trickle down effect of the Dietary Supplements Health and Education Act (DSHEA). Some think allowing qualified claims will lower standards for conventional foods.

Some think that dietary supplements need to be treated differently than conventional foods in terms of dosage. Most dietary supplements are in pill form and it is therefore easier to overdose than with consumption of food. Most consumers will become full before consuming enough of the food product to create an overdose situation.

Consumers view dietary supplements as different from conventional foods and therefore they must be treated differently.

Consumers are asking more questions about dietary supplements than about prescription drugs. Consumers clearly view dietary supplements differently than foods.

Summary of Discussion:

FDA heard the individual comments of participants that we need to proceed cautiously and carefully. The health professional organizations' individual representatives believe we need to establish definitions for what evidence is required to support a claim. They want a scientific foundation behind claims so consumers understand and are not mislead. Most importantly, FDA needs to carefully consider how to present the information to consumers and seriously consider the use of graphics in lieu of written statements.

FDA encouraged the participants to think about positive health claims; specifically those related to diet and disease relationships that should be allowed. FDA requested that these claims be submitted for consideration. The attendees were encouraged to send in comments to the docket.

Date: March 28, 2003
Time: 2:00 – 4:00 p.m.
Location: Conference Room 4B-047, Harvey W. Wiley Federal Building

Subject: FDA Initiative on Health Claims for Food Labels

Attendees:

Food and Drug Administration:
Lester Crawford; Joseph Levitt; Norris Alderson; William Hubbard; Michael Landa; Peter Salsbury; William Allaben; Steven Bradbard; Alan Rulis; Christine Taylor; Elizabeth Yetley; Kathleen Ellwood; Patricia Kuntze; Cynthia Wise; Mary Lacey Reuther, Susan Bernard

Federal Trade Commission:
Mary Engle; Pauline Ippolito

National Institutes of Health:
Wendy Johnson-Taylor

Industry Organizations:
Peter Barton Hutt, Grocery Manufacturers of America
Alison Kretser, Grocery Manufacturers of America
Regina Hildwine, National Food Processors Association
E. Linwood Tipton, International Dairy Foods Association
Cary Frye, International Dairy Food Association
Wendy Davis, Food Marketing Institute
Elizabeth Bell, General Mills
Robert Collette, National Fisheries Institute
Steve Grover, National Restaurant Association
Susan Harris, International Life Sciences Institute
James McCarthy, Snack Food Association
Elizabeth Campbell, AAC Consulting Group
Annette Dickinson, Council for Responsible Nutrition
Michael McGuffin, American Herbal Products Association
Jonathan W. Emord, Emord & Associates for American Herbal Products Association
Edward Johns, Herbalife International
Linda Suydam, Consumer Healthcare Products Association
Eve Bachrach, Consumer Healthcare Products Association
David Seckman, National Nutritional Foods Association*
Margaret Leahy, Ocean Spray Cranberry*
Carla McGill, Tropicana*
Janet Collins, Monsanto*

*Participated via phone.

Purpose: To brief the attendees on the Task Force and begin the process of hearing views on all aspects of the Task Force effort. Specifically, the Task Force wanted to hear the attendees' individual views on how to help facilitate the flow of information to consumers and about the role of sound dietary practices in achieving and maintaining good health, while assuring that such information is truthful, non-misleading, and based on sufficient scientific evidence.

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Overview on Health Claims for Food Labels
Informal Discussion with Participating Organizations
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Meeting Summary:

Dr. Crawford opened the meeting and provided information about the Task Force and its purpose. The Task Force is charged with developing a framework that will facilitate consumers' access to good information on food and dietary supplements that is scientifically based. The Task Force is also charged with developing a consumer studies research agenda aimed at providing research needed to determine how best to present scientifically-based information to consumers in a non-misleading way, and at identifying the kinds of information shown to be misleading to consumers. The Task Force will make recommendations to the Commissioner in June 2003. FDA plans to share the report and summaries of Task Force meetings with stakeholder organizations. The report will include recommendations on qualified claims for conventional foods and a consumer studies research agenda to determine what is misleading to consumers.

Dr. Christine Taylor provided a brief overview on Health Claims for Food Labels and the establishment of the Commissioner's Consumer Health Information for Better Nutrition Initiative. Dr. Taylor said that FDA issued guidance on qualified claims implementing the court decisions and was available on the FDA Internet site (See Guidance for Industry - Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements, December 18, 2002 at: http://www.cfsan.fda.gov/~dms/hclmgui2.html). Dr. Taylor also indicated that the Agency was considering guidance as well as regulations. Participants were encouraged to provide written comments on this initiative to the Public Docket (03N-0069).

Dr. Crawford led an informal discussion with the participating organizations that was framed around the following six questions. He encouraged the participants to submit comments to the docket to augment today's discussion. Highlights from points made by the stakeholders in the discussion are summarized below.

1) What body of scientific evidence do you think should be adequate for a qualified health claim?
2) What types of safety concerns should be factored into FDA's decision making?
3) What specific claims do you think are currently ready for consideration under the new guidance?
4) On what issues are disclaimers valuable, or not valuable, in preventing consumers from being misled, and do you have data to support your view?
5) What kinds of empirical data should FDA rely upon to show that consumers are, or are not, mislead by claims?
6) Should conventional foods and dietary supplements be treated the same or treated differently, and why?

Question 1: What body of scientific evidence do you think should be adequate for a qualified health claim?

It was suggested that the standards for making claims within advertisements should be the same as those for making claims on food labels.

It was stated that the evidence needs to be credible and that there is concern about an artificial level of evidence. There should be no reason not to permit the qualified health claim as long as there is some explanatory information or disclaimer accompanying the claim.

There is concern about claims being made that are followed by a disclaimer. It appears to be "good news" followed by "bad news."

It was suggested that the claim itself determines what the scientific evidence should be and the current status of the supporting science.

Many sources of scientific evidence exist. It was stated that the evidence comes from two bodies: historical documents and contemporary documents.

It was stated that there are instances where non-governmental authoritative bodies have completed a detailed analysis of a health benefit situation. In these instances, some felt that claims should be permitted. For example, "the American Heart Association says...."

It was stated that claims need to be simplified and without lines of qualifications. In cases such as menus, use of complex statements wouldn't be practical.

A one-size fits all standard approach will not work. The multifaceted nature argues for the need to accommodate claims on a case-by-case basis.

It was stated that food labels are carefully planned and in the market place for months, if not years. Companies are not going to jeopardize their reputations for

unsupported claims. Labeling is much different than advertising, in terms of duration of use.

Question 2: What types of safety concerns should be factored into FDA's decision making?

It was stated that every type of safety concern should be addressed. Consideration should also be given to the issue of consumers changing their eating habits based on a claim.

It was felt that safety standards with respect to substances and the adulteration provisions would be a good place to start in addressing safety concerns. Ingredients should be approved food additives, Generally Recognized As Safe (GRAS) or prior sanctioned. First the substance must be safe - FDA should do what it always does for safety reviews.

Safety concerns related to special populations must also be factored into the decision-making.

It also needs to be recognized that there are different concerns when compounds are added to foods versus inherent nutrients. For example, milk is naturally full of nutrients.

Concern was expressed that the approach needs to be flexible. Claims can't be misleading and must be truthful. For example, pretzel products are not permitted to make a folic acid claim. A case-by-case consideration would provide the flexibility to make this type of claim.

There are differences in safety issues and health claim issues. Nutrition is about the quantity of consumption of nutrients. If taken literally, any health claim could be detrimental to some consumer. It was felt that safety concerns should be separate from health claims. Safety issues need a higher degree of science than health claims. The product must be made safe first and then the qualified health claim can be developed.

As another example, health claims are now permitted for alcoholic beverages. However, the permitting of a health claim does not indicate support or promotion for consumers to go out and consume large quantities of alcohol.

Emerging safety issues shouldn't be ignored but should not be dealt with in a health claim.

Most supported a position of permitting more information for consumers rather than less.

Question 3: What specific claims do you think are currently ready for consideration under the new guidance?

It was suggested that a dairy claim regarding hypertension was ready for consideration.

Most felt that qualified claims being made on dietary supplements were equally applicable to foods and qualified claims like these should be considered.

It was suggested that the Omega-3 fatty acid claim as it relates to fish consumption should be considered.

Concern was expressed that there was the potential for the Agency to receive many health claim petitions and this may be a burden on FDA resources. It was suggested that perhaps FDA should consider claims in a broader scope when something comes in for a specific food. FDA should take an approach of applying the claim to all foods for which it would apply.

The industry representatives suggested that a separate and simpler process for reviewing qualified health claims is needed and must be different than those claims seeking the higher "significant scientific agreement" standard. Companies would be willing to stipulate up front in a petition that they are seeking a qualified health claim, not an unqualified one.

Question 4: On what issues are disclaimers valuable, or not valuable, in preventing consumers from being misled, and do you have data to support your view?

It was suggested that first you must look at the claim to see if the information is included.

There was general objection to the use of prescriptive negative language for disclaimers. The proposed footnote for trans fatty acid was cited as an example of a negative disclaimer.

It was suggested that the court decisions do not require the use of good news and bad news on health claims and disclaimers. It was suggested the standard for health claims should be accurate, truthful and not misleading.

It was stated that statements could be made and understand by a "reasonable consumer" without prescriptive negative language.

It was also stated that a "reasonable consumer" doesn't mean that there wouldn't be someone who doesn't understand.

Adequate data, protocols, following good laboratory procedures (GLPs) are used to determine what is credible scientific evidence. It was stated that health claims and qualified health claims need to have respect in the scientific community. Claims where there is only a smidgeon of evidence wouldn't be regarded as credible. It was stated that those who market foods wouldn't be eager to put negative statements on a label. There is a natural reluctance in the conventional food industry to put qualified health claims on foods. It was thought that if the disclaimers became so onerous that there would be an effort to move the qualified health claim into a structure/function claim.

Question 5: What kinds of empirical data should FDA rely upon to show that consumers are, or are not, mislead by claims?

There was concern that the questions suggests proof that consumers are not misled would be part of the incoming petition. It was suggested that the actual claim a company wishes to make contain the science information and that should suffice. The issues about the number of studies, is the evidence, etc. and should be part of the claim and not a disclaimer.

The standard used by the FTC was described as not being pre-emptive or having a pre-approval action and has been successful for advertising.

It was stated that there are distinctions between private and public speech. The First Amendment protects the language in a qualified health claim regardless of whether a consumer doesn't understand a claim so long as they are not misled. FDA must have empirical evidence to support that a claim is misleading. It was indicated that the petitioner's claim is the petitioner's property and the petitioner must be willing to accept modifications to the language.

There was a discussion on the process that needs to be developed and it was suggested that FDA and the petitioner use a cooperative approach if there are issues regarding a claim. It was stated that handling of qualified health claims be on a case-by-case basis and that a general rule that applies to all claims not be made. It was also suggested that FDA meet with the petitioner.

It was stated that it was important to recognize the distinction between FDA and FTC regulations and procedures. FTC reviews advertisements after publication and FDA is required to review claims prior to use on a label.

It was suggested that individual companies may have information relating how consumers perceive particular claims. However, this type of information is usually considered proprietary.

Question 6: Should conventional foods and dietary supplements be treated the same or treated differently, and why?

All of the industry representatives felt that dietary supplements and conventional foods should be treated the same when a specific nutrient is the subject of the claim. For example, claims allowed for calcium supplements should be able to be made on milk.

It should be recognized that there may be situations that necessitate a case-by-case consideration of a specific claim.

Summary of Discussion:

The participants were appreciative of FDA's efforts to include them and commended FDA on its efforts.

Mr. Levitt closed the meeting by thanking the attendees and once again encouraged the participants to submit written comments to the public docket. A summary of this meeting will be sent to the docket.

Date: April 22, 2003
Time: 2:00 – 4:00 p.m.
Location: Conference Room 4B-047, Harvey W. Wiley Federal Building

Subject: FDA Initiative on Health Claims for Food Labels

Attendees:

Food and Drug Administration:
Joseph Levitt; William Hubbard; Michael Landa; Peter Salsbury; William Allaben; Steven Bradbard; Alan Rulis; Christine Taylor; Elizabeth Yetley; Kathleen Ellwood; Joanne Lupton; Patricia Kuntze; Cynthia Wise

Federal Trade Commission:
Mary Engle

National Institutes of Health:
Wendy Johnson-Taylor

Consumer Community Organizations:
Rebecca Burkholder, National Consumers League
Sandra Eskin, AARP
Adolph P. Falcon, National Alliance for Hispanic Health
Ilene R. Heller, Center for Science in the Public Interest
Bruce Silverglade, Center for Science in the Public Interest
Frances Smith, Consumer Alert

Purpose: To brief the attendees on the Task Force and begin the process of hearing views on all aspects of the Task Force effort. Specifically, the Task Force wanted to hear the attendees' individual views on how to help facilitate the flow of information to consumers about the role of sound dietary practices in achieving and maintaining good health, while assuring that such information is truthful, non-misleading, and based on sufficient scientific evidence.

Agenda:
Welcome and Introductions
Overview on Health Claims for Food Labels
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Meeting Summary:

Mr. Levitt opened the meeting and thanked everyone for taking the time to participate. Mr. Levitt explained that Dr. Crawford has been actively involved in this initiative, however, he was not able to participate today because he was leading a delegation going to Mexico to discuss food safety issues related to cantaloupes.

Dr. Christine Taylor provided a brief overview on Health Claims for Food Labels and the establishment of the Commissioner's Consumer Health Information for Better Nutrition Initiative. Dr. Taylor said that FDA issued guidance on qualified claims implementing the court decisions and was available on the FDA Internet site (See Guidance for Industry - Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements, December 18, 2002 at: http://www.cfsan.fda.gov/~dms/hclmgui2.html). Dr. Taylor also indicated that the Agency was considering guidance as well as regulations. Participants were encouraged to provide written comments on this initiative to the Public Docket (03N-0069).

Before the discussion of the questions began, Mr. Bruce Silverglade requested permission to make an opening statement. Mr. Silverglade indicated that the Center for Science in the Public Interest along with Public Citizen have submitted comments to the docket. Mr. Silverglade indicated that they were concerned about the approval process and believed that anything short of notice and comment rulemaking would be illegal. Mr. Silverglade indicated that the comments they submitted to the public docket explained their position in detail. Mr. Levitt thanked Mr. Silverglade for submitting comments to the public docket and encouraged the other participants to submit comments as well.

Mr. Levitt led an informal discussion with the participating organizations framed around the following six questions. He encouraged the participants to submit comments to the docket to augment today's discussion. Highlights from the points made by the stakeholders in the discussion are summarized below.

1) What body of scientific evidence do you think should be adequate for a qualified health claim?
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6) Should conventional foods and dietary supplements be treated the same or treated differently, and why?

Question 1: What body of scientific evidence do you think should be adequate for a qualified health claim?

It was stated that in general peer reviewed, verifiable and repeated studies would be the body of evidence to be considered. It was also stated that these studies would use methodology that was generally accepted.

It was stated that these studies should also include minority populations.

There was concern about FDA's reaction and interpretation of the court's decision regarding the weight of scientific evidence. It was stated that the court addressed a case with some evidence and didn't discuss a case with little or no evidence.

There was concern about the approval of qualified health claims before FDA has developed a complete process. The Agency was encouraged to resolve all issues and develop policies before claims are reviewed and considered.

It was stated that the Federal Trade Commission (FTC) standard of "competent and reliable evidence" might not be appropriate for FDA to use. NLEA provides an educational component and the FTC standard does not include one.

It was stated that reliable evidence does not mean one (1) study. But does it mean two? The definition of reliable evidence is a moving target and there is not agreement on what it means.

It was stated that the Center for Science and the Public Interest (CSPI) has petitioned FTC at least five times to enforce their health claim advertising policy for foods.

There was discussion of an FTC study that looked at print advertisements making health claims. The study did not include television advertisements. It was stated that these studies were flawed because they did not include the television advertisements and did not provide an accurate picture of what consumers understand and take away from health claim advertisements.

A stakeholder said the FTC position is that more valid information is useful to consumers than less information. It was stated that this approach is supported and restricting information is harmful.

It was stated that truthful information is useful to the consumer and misleading information would be considered fraudulent.

It was stated that the FTC has not taken enforcement action on food ads. It was stated that FTC would leave the determination of significant scientific agreement up to FDA. However, FTC would enforce advertisement of foods and health claims. It was also stated that FDA doesn't allow for unapproved health claims on the labels, however, the FTC would allow for their use in advertisement.

It was stated that FDA needs to understand what kinds of health information consumers want. It was also stated that the health claim needs to be helpful to the consumer and that consumers need to understand the context of the information.

Question 2: What types of safety concerns should be factored into FDA's decision making?

It was stated that FDA needs to be concerned with the tolerable upper intake levels of the nutrient/ingredient to be used in the health claim. When FDA reviews a food additive petition, consumption data is reviewed and it was suggested that the same be done for health claim petitions.

Concern was expressed that consumers may chose to consume food instead of taking conventional medicines. For example, a consumer may eat oatmeal to lower cholesterol instead of taking prescription medications prescribed by their physician. These kinds of issues need to be considered when considering approval of a qualified health claim.

It was stated dietary supplement and food interactions need to be factored into FDA's decision making.

It was stated that interactions with food products and medications need to be factored into the decision-making. Also concern was stated about children and functional foods.

It was stated FDA needs to consider problems with imported foods that contain certain ingredients and contaminants that can have interactions.

It was stated FDA needs to consider whether the consumer is being provided too much information. Concern was expressed that consumers may be on information over-load and consumers may start to ignore all health claims.

It was stated FDA needs to consider the broader educational issues and not just education through use of the food label.

Question 3: What specific claims do you think are currently ready for consideration under the new guidance?

It was stated that FDA must first answer these questions being discussed today and develop a policy and process before it moves to approving any qualified health claims.

It was stated that it is risky to allow claims that may be proven wrong later. An example given was Beta carotene, which initially looked good but later studies showed it increased the risk of cancer.

It was stated that the mercury issues need to be factored into any decision regarding a future allowed qualified health claim related to omega-3 fatty acids and fish. The mercury issues are safety factors that need to be considered.

It was stated that consumer studies are needed to see what consumers understand and FDA must consider whether qualified health claims can help consumers.

Question 4: On what issues are disclaimers valuable, or not valuable, in preventing consumers from being misled, and do you have data to support your view?

It was stated that AARP had conducted a preliminary telephone study providing a claim with two different types of language. The preliminary study showed that consumers thought that a qualified claim had more evidence than an unqualified claim. They will provide this information to the docket.

It was stated that consumer studies are needed on disclaimers to get the empirical evidence on what consumers understand and what consumers interpret certain things to mean.

It was stated that the qualified health claim petition should contain consumer studies to support that the claim is not misleading.

It was stated that the Agency should proceed on a case-by-case basis for now. It was suggested that the Agency maybe able to establish patterns and do guidance on what misleads and what doesn't in the future.

It was stated that the type of disclaimer needs to be tied to the scientific evidence and that the petitioner should submit evidence supporting the claim is not misleading.

It was also suggested that perhaps a color coded type system would be easier for consumers to understand the scientific evidence presented for a qualified health claim. For example, use Gold for a high level of scientific support and silver and bronze for lesser levels of support.

It was stated that consumers look to the Agency for advice and therefore, consumers probably take the next step when a claim is made and believe the Agency supports the claim.

Concerned was expressed about whether consumers would read the disclaimers. Studies show for over-the-counter (OTC) drugs only 15% of consumers read the disclaimers and side effects information.

FTC stated that it has conducted research on disclaimers, which indicates that it is often difficult to communicate disclaimers effectively. It may be preferable to incorporate qualifiers into the statement instead of having them as a follow-on statement. It was stated that this is important research for FDA to do.

Concern was expressed about the number of different qualifiers that could be used and consumer ability to understand the differences and what they mean. It was suggested that standardization of qualifiers be considered.

It was stated that generic qualifiers form a consumer copy test, in theory, would be useful and that the generic qualifiers need to be further tested on consumers.

Question 5: What kinds of empirical data should FDA rely upon to show that consumers are, or are not, mislead by claims?

It was stated that mall intercept studies are much more effective than telephone studies.

It was stated that focus groups cannot be the only source of data.

It was also stated that the data need to factor in and consider more than just the "reasonable person standard" but need to consider children, disabled, those with health issues and those for whom English is not the primary language.

It was stated that Web studies are becoming more acceptable, however not all groups of consumers are using the Web at the same rate.

It was also stated that post market studies demonstrating consumer understanding and the effectiveness of the claim are important. It was stated that industry should be required to monitor the science that supported the claim and if it changes they would need to correct the label information. There should be a vehicle to deal with false and misleading claims.

It was also stated that post market advertising monitoring needs to be done to ensure advertising doesn't negate the qualifying statement.

Question 6: Should conventional foods and dietary supplements be treated the same or treated differently, and why?

It was stated that foods and dietary supplements are different "animals" and therefore should be treated differently. Foods are in the refrigerator and you can open the door and just get it.

It was also stated that there is more abuse with dietary supplements than foods.

It was also stated that very few ingredients in food have safety issues, except allergen issues or chronic impacts such as obesity. The safety concerns for dietary supplements are greater.

It was stated that everybody buys and consumes food but only 50% of consumers buy supplements. Everybody eats but not everybody needs supplements.

It was also stated that most conventional foods don't pose the same interaction problems with drugs as dietary supplements. However, there are a few conventional foods such as grapefruit juice that interact with many medications and consumers don't know that.

It was stated that most consumers think dietary supplements are closer to over-the-counter drugs than to food.

Summary of Discussion:

Mr. Levitt asked each of the participants to provide their individual summary thoughts.

Individual commenters encouraged the agency to answer all the questions discussed today before approving any qualified health claims. Commenters encouraged the agency to consider including structure / function claims into the process. Structure/function claims are becoming used more and more.

The individual commenters encouraged the agency to consider something easy for consumers to see and understand and to establish some type of standardized system for qualified health claims and disclaimers.

It was suggested that through the use of good, valid qualified health claims good nutrition habits could be achieved.

The Agency was encouraged not to lose sight of the importance of testing the language on consumers, to conduct more general research on content and context of claims, and to require the petitioner to provide studies to prove what language works best and is not misleading.

The Agency was reminded that overall, consumers have information overload and we need to keep this in mind when reviewing and approving qualified health claims.

The Agency was encouraged to standardize the language and to repeat the same language over again and again so that consumers will learn and understand what the language means. Consumer education will also be needed.

The Agency was encouraged to use a visual or graphic presentation to ensure that non-English speaking or other learning disable persons could understand a qualified health claim.

Mr. Levitt closed the meeting by thanking the attendees for participating and once again encouraged the participants to submit written comments to the public docket. A summary of this meeting will be sent to the docket.

Date: May 14, 2003
Time: 2:00 – 4:00 p.m.
Location: Conference Room 4B-047, Harvey W. Wiley Federal Building

Subject: FDA Initiative on Health Claims for Food Labels

Attendees:

Food and Drug Administration:
Lester Crawford; Joseph Levitt; William Hubbard; Michael Landa; Peter Salsbury; William Allaben; Steven Bradbard; Bob Lake; Christine Taylor; Elizabeth Yetley; Kathleen Ellwood; Patricia Kuntze; Cynthia Wise; Donna Robie; Joanne Lupton; Tomas Philipson; Judy Blumenthal; Theresa Mullin*; Susan Bernard*

Federal Trade Commission:
Mary Engle; Pauline Ippolito

National Institutes of Health:
Van S. Hubbard

Academia and Research Organizations:

Sara Eggars, Carnegie Mellon University*
John W. Erdman, University of Illinois at Urbana-Champaign*
Deborah Frisch, National Science Foundation
David Lineback, Joint Institute for Food Safety and Applied Nutrition
Norman Krinsky, Tufts University School of Medicine*
Bernadene Magnuson, University of Maryland
Sanford A. Miller, CNFP, Virginia Polytech Institute
Linda Meyers, National Academy of Sciences
Katherine McComas, University of Maryland
Dave Schmidt, International Food Information Council Foundation
Maureen L. Storey, Virginia Tech
Cheryl Toner, International Food Information Council Foundation

*Participated via phone.

Purpose: To brief the attendees on the Task Force and begin the process of hearing views on all aspects of the Task Force effort. Specifically, the Task Force wanted to hear the attendees' individual views on how to help facilitate the flow of information to consumers about the role of sound dietary practices in achieving and

maintaining good health, while assuring that such information is truthful, non-misleading, and based on sufficient scientific evidence.

Agenda: Welcome and Introductions
Overview on Health Claims for Food Labels
Informal Discussion with Participating Organizations
Summary

Meeting Summary:

Dr. Crawford opened the meeting and provided information about the Task Force and its purpose. The Task Force is charged with developing a framework that will facilitate consumers' access to good information on food and dietary supplements that is scientifically based. The Task Force is also charged with developing a consumer studies research agenda aimed at providing research needed to determine how best to present scientifically-based information to consumers in a non-misleading way, and at identifying the kinds of information known to be misleading to consumers. The Task Force will make recommendations to the Commissioner in June 2003. FDA plans to share the report and summaries of Task Force meetings with stakeholder organizations. The report will include recommendations on qualified claims for conventional foods and a consumer studies research agenda to determine what is misleading to consumers.

Dr. Christine Taylor provided a brief overview on Health Claims for Food Labels and the establishment of the Commissioner's Consumer Health Information for Better Nutrition Initiative. Dr. Taylor said that FDA issued guidance on qualified claims implementing the court decisions and was available on the FDA Internet site (See Guidance for Industry - Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements, December 18, 2002 at: http://www.cfsan.fda.gov/~dms/hclmgui2.html). Dr. Taylor also indicated that the Agency was considering guidance as well as regulations. Participants were encouraged to provide written comments on this initiative to the Public Docket (03N-0069).

Dr. Crawford led an informal discussion with the participants framed around the following six questions. He encouraged the participants to submit comments to the docket to augment today's discussion. Highlights from points made by the stakeholders in the discussion are summarized below.

1) What body of scientific evidence do you think should be adequate for a qualified health claim?
2) What types of safety concerns should be factored into FDA's decision making?
3) What specific claims do you think are currently ready for consideration under the new guidance?

4) On what issues are disclaimers valuable, or not valuable, in preventing consumers from being misled, and do you have data to support your view?
5) What kinds of empirical data should FDA rely upon to show that consumers are, or are not, mislead by claims?
6) Should conventional foods and dietary supplements be treated the same or treated differently, and why?

Question 1: What body of scientific evidence do you think should be adequate for a qualified health claim?

It was suggested that the claim itself would determine the body of evidence needed. For example a claim like "All Bran cures cancer" would obviously need significant evidence compared to a claim such as "high fiber helps your colon" that would probably need less evidence to substantiate.

It was stated that there needs to be an understanding of significant scientific evidence versus what weight of the evidence means. It would seem that weight of the evidence is vague, even "more fuzzy" than significant scientific evidence.

It was stated that FDA needed to decide if a disclaimer is a warning or for educational purposes.

It was stated that there are existing paradigms that could be applied. There are academic standards to be used – Peer Review should be used for reliability. It was stated that there are groups who don't want to recognize peer review but it is really the gold standard. FDA needs to also consider the consequences of being wrong.

It suggested that the Task Force read the 1998 Diet and Health Report by the Institute of Medicine on emerging science that compared and evaluated scientific evidence. In these studies the gold standard was random, controlled trials with at least 1000 participants.

It was stated that there will be many claims submitted that would not have the kind of double-blind trials needed to meet a gold standard. FDA was urged to avoid the "snake oil scenario."

Question 2: What types of safety concerns should be factored into FDA's decision making?

It was stated that safety concerns should always be considered in reviewing a claim. It was stated that a situation in which the Agency would not consider safety concerns is unimaginable.

It was stated that this is a risk-risk paradigm. What are the risks of allowing the claim versus the risks of not allowing the claim?

It was stated that the approval of a claim should probably be based on the consequences of not doing it.

It was stated that FDA needs to avoid the "Snake Oil" scenario and the mistaken assumption of "if a little is good then a lot must be better."

It was stated that the effective safe dose must be considered, especially for certain subpopulations. The odds of eating too much of a conventional food probably won't be an issue. However, with supplements added to food, manufacturers should be responsible for ensuring the safety. Can the agency "control" levels of fortification?

It was stated that the Agency needed to have controls built into the regulatory framework. If the Agency can have some control of an ingredient added to food the issue of overdose isn't as important. If the Agency doesn't have some control then the issue of overdose is a significant factor.

It was stated that the Agency needs to consider the risks if the ingredient is added and the risks if the ingredient is not added.

It was also stated that the Agency needs to consider significant long-term testing. How many years, studies, animals, etc. are needed?

Question 3: What specific claims do you think are currently ready for consideration under the new guidance?

It was stated that the following claims are ready for consideration:

- Soy and Breast Cancer
- Calcium and Hypertension
- Lycopene and Prostrate Cancer
- Processed Tomato Products and Prostrate Cancer

It was stated that we should not disallow a claim just because it may have adverse effects or drug interactions for a small percentage of the population. Soy and breast cancer with a warning on using tamoxifin was cited as an example.

Question 4: On what issues are disclaimers valuable, or not valuable, in preventing consumers from being misled, and do you have data to support your view?

It was stated that, in general, consumers are confused about what information on a food label is FDA approved and what is just a marketing statement. It was suggested that FDA would need to clarify what it has evaluated for consumers.

It was stated that disclaimers need to be short and not cover the whole package. Beware of information overload.

It was stated that there isn't a lot of research demonstrating what information consumers read and use on the food label.

It was stated that FDA needs to be careful with the use of disclaimers. The Agency needs to make sure it is not endorsing or appearing to endorse a particular product. Also need to decide how to draw the line on what is a disclaimer versus a warning statement.

It was stated that it should be incumbent upon the manufacturer to provide information showing the claim language is not misleading. It was stated that manufacturers do consumer research and marketing departments would have this type of information.

It was stated that consumer studies on generic statements could be done, however, may of the claims and disclaimers will be so specific that generic studies may not truly address the issues of whether a statement is understood or not.

It was stated that consumers usually seek out products because they have heard about the product somewhere (i.e. friends, family, magazine, television), not because they happen across it at the grocery store. It was stated that FDA needs to be careful that the health claims authorized don't confirm these notions for consumers.

It was stated that the claim must be supported by some define-able body. Consumers are looking for an authoritative body to make the claim and FDA should decide what to do for the good of the public health.

It was stated that FDA must "pick" qualifiers that have meaning to the consumer. It was stated that FDA should be part of a qualifier.

It was stated the use of a rating system may not be useful—consumers are still having trouble understanding the Food Pyramid.

It was stated that there is some research demonstrating that the use of scales is more easily understood that written words.

It was stated that the consequences and risk of a product must be clearly explained to the consumer as well.

It was explained that the burden of providing truthful information falls on all parties involved. The Agency has the responsibility to enforce the laws and the manufacturers have the responsibility to ensure the information is truthful. Industry should provide research to FDA.

It was stated that terms on disclaimers such as "moderate / strong" are better understood than "limited / preliminary."

The question of whether it was possible to have both positive and negative indicators on the label was asked. And, when does information on a label become a "warning?"

It was stated that consumers with terminal illnesses might be more willing to accept and try something because of the claim more so than the general population.

There were mixed views on rating systems for consumers. It was stated that an evaluation system/rating system is do-able. It was further stated that it would be helpful to do testing with consumers before going forward with the concept to determine if it would be useful to consumers and determine if they would use it.

It was stated that FDA needed to consider whether the rating system was intended to help consumers or was it to be a tool used by FDA to make it feel better about the language of a claim.

It was stated the perhaps FDA should consider the use of recognized symbols to denote an approved health claim and a rating scale for a qualified claim.

It was stated the message could be conveyed to consumers, however it needs to be simple, generic and straightforward. It was stated that consumers would use it if it is simple and there is an accompanying educational program.

It was stated that consumers accept the nutrition facts panel neutrally. However, many consumers believe there are motives behind ads.

Question 5: What kinds of empirical data should FDA rely upon to show that consumers are, or are not, misled by claims?

It was stated that FDA should rely on three types of consumer studies: the standard focus groups—in at least three major cities; Internet based research and standard telephone surveys.

It was stated that there is standard research conducted by companies. Companies place a product in the home and see if consumers will buy it or not.

It was stated that studies using various labels and claims are needed to demonstrate what resonates with consumers and what doesn't.

It was stated that studies should include groups of consumers who are seeking out these types of products as well as the general consumers.

It was stated that research should be done on both generic and specific language claims.

It was stated that the food label serves as a reminder to consumers of information that they have gotten from other sources.

It was stated that a media analysis should be done to capture what types of information is out there. A lot of what consumers know or get is from the media.

It was stated that FDA needs to be careful and ensure that the statements don't become the "issue of the day." It may be possible to use other communication forms to address the issue-of-the-day type statements.

It was stated that gathering scientific evidence and information needed will take a long time.

It was stated that we need to consider not only whether a consumer understands the label and claim but also whether the information changes behavior. Do consumers buy or not buy based on the claim. It was suggested that data on the purchase or non-purchase of an item could be used as an indicator and should FDA test to see if consumers would buy a product.

Question 6: Should conventional foods and dietary supplements be treated the same or treated differently, and why?

It was stated that ultimately dietary supplements, conventional foods and functional foods will need to be treated the same. If the Agency doesn't handle them the same, it will create a "patchwork quilt" system.

It was stated that in some cases it has been difficult to distinguish between a dietary supplement and conventional food.

It was stated that the health claim in and of itself wouldn't change the health of the public. But it can be one tool used in combination with other tools and education that could make a difference.

Summary of Discussion:

Dr. Crawford closed the meeting by thanking the attendees and once again encouraged the participants to submit written comments to the public docket.

A summary of this meeting will be sent to the docket.